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~~ANASTOMOSIS MEMBER FOR ANASTOMOSIS OF BLOOD VESSELS
AND ANASTOMOSIS METHOD USING THE ANASTOMOSIS MEMBER~~

Background of the Invention:

This invention relates to an anastomosis member for anastomosing blood vessels and an anastomosis method using the anastomosis member.

An anastomosis member serves to perform the anastomosis of two normally distinct hollow organs, such as blood vessels, to form a passage therethrough.

In a conventional surgical operation, the anastomosis of the blood vessels is generally carried out by suturing with a needle and a suture filament. When the blood vessels are anastomosed or joined to each other, a blood flow must temporarily be interrupted. If an increased number of sites are required to be anastomosed, the time of interrupting the blood flow is unfavorably extended.

In the surgical operation of a living body, it is required to use auxiliary means such as extracorporeal circulation or controlled hypothermia if it is presumed that the time of interrupting the blood flow exceeds an allowable time for the living body. It is difficult to suture the blood vessels under arteriosclerosis with the needle and the suture filament if those vessels have calcification. In case where the blood vessels are fragile, they must be reinforced to avoid the risk.

The technique of using a stent in the anastomosis of the blood vessels with heavy calcification is reported. In this technique, an artificial blood vessel is inserted into a host blood vessel to partially overlap each other. The stent is retained in the blood vessels at the overlapping portion to press-fit the blood

vessels to each other. Thus, the anastomosis is carried out. For example, a type of the stent is disclosed in U.S. Patent No. 6,017,362.

In the technique of anastomosing the blood vessels by the use of the stent, the blood vessels are simply press-fitted by the elasticity of the stent and may be undesirably released from each other by, for example, the beat of the artery. Thus, the anastomosis by the use of the existing stent is insufficient in fixing or engaging force and in reliability.

Summary of the Invention:

It is therefore a technical object of this invention to provide an anastomosis member capable of safely and quickly carrying out the anastomosis of blood vessels and to provide an anastomosis method using the anastomosis member.

It is another object of this invention to provide an anastomosis member improved in reliability by the use of a technique of applying an engaging force only to an adventitia of a blood vessel which is stronger than an intima of the blood vessel and to provide an anastomosis method using the anastomosis member.

It is still another object of this invention to provide an anastomosis member capable of carrying out the anastomosis of blood vessels substantially equal in outer diameter and in inner diameter and to provide an anastomosis method using the anastomosis member.

According to this invention, there is provided an anastomosis member to be arranged at an anastomosed site of first and second blood vessels to carry out the anastomosis of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising at least one plate member to be brought into contact with both of the first and the second blood vessels, the plate member having a plurality of protrusions formed on at least one of opposite surfaces thereof to be engaged with at least one of the first and

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the second blood vessels so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

Preferably, the anastomosis member has a plurality of the generally cylindrical bodies and at least one connecting member connecting the generally cylindrical bodies to one another.

Preferably, the anastomosis member has an elasticity so as to be compressed and expanded in diameter.

Preferably, the anastomosis member has a stress-strain characteristic including a plurality of different kinds of regions at least corresponding to a low-rigidity part deformable along the curvatures of the first and the second blood vessels to be tightly fitted thereto, and a spring region which is compressible and self-expandable in diameter.

Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a zigzag pattern.

Preferably, the generally cylindrical body comprises at least one plate member wound into a helical shape

Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a lattice pattern.

Preferably, the generally cylindrical body comprises a plurality of the plate members connected to one another in a rhombic pattern.

Preferably, the generally cylindrical body comprises a plurality of the plate members arranged in parallel to one another and a plurality of connecting members connecting the plate members to one another.

Preferably, each of the connecting members is an elastic wire member.

Preferably, the plate member is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

According to this invention, there is also provided an anastomosis device for use in the anastomosis of first and second blood vessels, the

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anastomosis device comprising a combination of an anastomosis member arranged on an outer surface of at least one of the first and the second blood vessels and a stent to be arranged in a lumen of the at least one of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising at least one plate member to be brought into contact with both of the first and the second blood vessels, the plate member having a plurality of protrusions formed on at least one of opposite surfaces thereof to be engaged with at least one of the first and the second blood vessels.

Preferably, the stent is made of a stainless steel plate or a shape memory alloy selected from a TiNi alloy and a beta Ti alloy.

Preferably, the anastomosis device further comprises an additional blood vessel.

According to this invention, there is also provided an anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis member to be arranged at an anastomosed site of the first and the second blood vessels, the anastomosis member having a generally cylindrical body comprising a plate member with a plurality of protrusions formed on at least one of opposite surfaces thereof, the method comprising the steps of inserting the anastomosis member into lumens of the first and the second blood vessels; bringing the plate member into contact with at least one of the first and the second blood vessels; and engaging the first and the second blood vessels with the protrusions so as to prevent the dislocation of the first and the second blood vessels at the anastomosed site.

Preferably, the anastomosis method further comprises the steps of inserting an end portion of one of the first and the second blood vessels into the lumen of the other blood vessel so that the end portions of the first and the second blood vessels overlap each other with the protrusions engaged with at least one of the first and the second blood vessels.

Preferably, each of the plate members is sutured by a fastening member to one of the first and the second blood vessels in at least one position in the anastomosed site, the protrusions being formed only on one surface of the plate member which faces the other of the first and the second blood vessels at the anastomosed site.

According to this invention, there is also provided an anastomosis method for the anastomosis of first and second blood vessels by the use of an anastomosis device to be arranged at an anastomosed site of the first and the second blood vessels, the anastomosis device comprising a combination of an anastomosis member and a stent, the anastomosis member comprising a plate member with a plurality of protrusions formed on at least one of opposite

Preferably, the anastomosis method further comprises the steps of placing an additional blood vessel on the outside of the anastomosis member arranged around the outer surfaces of the first and the second blood vessels; and engaging the anastomosis member and the additional blood vessel with the protrusions.

Preferably, the fastening member is a filament or a strap.

Fig. 1 is a perspective view of an astomosis member according to a first embodiment of this invention:

Fig. 3 is a perspective view of an anastomosis member according to a third embodiment of this invention;

Fig. 5 is a perspective view of an anastomosis member according to a fifth embodiment of this invention:

At first referring to Fig. 1, an anastomosis member 11 according to a first embodiment of this invention has a generally cylindrical body comprising a plurality of plate members or sections 11a connected to one another in a zigzag pattern extending along a cylindrical surface of an imaginary tube. Each of the

plate members 11a has opposite surfaces having a plurality of protrusions 11b formed thereon.

The anastomosis member 11 is prepared in the following manner. At first, the plate members 11a are formed. For example, each of the plate members 11a comprises a strip-like metal plate having a thickness of 0.2mm and a width of 2.0mm. Each of the protrusions 11b has a height of $70\mu\text{m}$ and a diameter of $30\mu\text{m}$. The protrusions 11b are arranged at a pitch of 0.3mm on the opposite surfaces of each plate member 11a. Thereafter, the plate members 11a are connected at their ends to one another by welding to extend in a zigzag pattern and to form the generally cylindrical body as the anastomosis member 11.

Alternatively, the anastomosis member 11 may be prepared from a sheet-like plate material. At first, the protrusions 11b are formed on the plate material. By the use of a laser or wire electric discharge, the plate material is cut into a zigzag pattern and then rolled into a cylindrical shape. Finally, rolled ends are welded to each other.

For example, the anastomosis member 11 thus prepared forms an imaginary tube having a cylindrical diameter of 8mm and an axial length of 10mm. The anastomosis member 11 is elastically variable in shape and in diameter.

The anastomosis member 11 can be produced in a different manner. Specifically, the plate member 11a is made of a stainless steel material (SUS316) subjected to annealing and having a low rigidity. For example, the anastomosis member 11 has a cylindrical diameter of 6.5mm and an axial length of 10mm.

Alternatively, the anastomosis member 11 may be produced by bending a single long strip-like stainless steel plate in a zigzag pattern having a plurality of short strip-like plate sections 11a and then rounding the zigzag pattern of the

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stainless steel plate into a cylindrical shape.

In the first embodiment, the anastomosis member 11 has a zigzag pattern. However, the anastomosis member 11 may have various other patterns which will be described below.

Referring to Fig. 2, an anastomosis member 12 according to a second embodiment of this invention has a generally cylindrical body comprising a helical coil formed by bending or winding a single long strip-like plate member 12a. Like in the first embodiment, the plate member 12a is provided with a plurality of protrusions 12b formed on opposite surfaces thereof. Instead of the single plate member 12a as the helical coil having a predetermined length, the anastomosis member 12 may comprise a plurality of helical coil elements which are connected in series to one another.

Referring to Fig. 3, an anastomosis member 13 according to a third embodiment of this invention has a generally cylindrical body comprising a plurality of strip-like plate members 13a connected to one another in a rhombic or a lattice pattern. Like in the foregoing embodiments, the plate member 13a is provided with a plurality of protrusions 13b formed on opposite surfaces thereof.

Referring to Fig. 4, an anastomosis member 14 according to a fourth embodiment of this invention has a generally cylindrical body comprising a plurality of strip-like plate members 14a equal in length and arranged in parallel to one another with an angular space kept from one another. These plate members 14a are connected by a plurality of wire connecting members 14c to form the generally cylindrical body as the anastomosis member 14. Like in the foregoing embodiments, the plate member 14a is provided with a plurality of protrusions 14b formed on its opposite surfaces.

For example, each of the plate members 14a comprises a stainless steel plate subjected to annealing and having a low rigidity. For example, each of the

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It is noted here that the shape of the anastomosis member 14 is not restricted to that illustrated in Fig. 4. The connecting member 14c can be

Referring to Fig. 5, an anastomosis member 15 according to a fifth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 15c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 11 in Fig. 1. The connecting portion 15c is made of a material same as that of plate members 11a.

Referring to Fig. 6, an anastomosis member 16 according to a sixth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 16c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 12 in Fig. 2. The connecting portion 16c is made of a material same as that of plate members 12a.

Referring to Fig. 7, an anastomosis member 17 according to a seventh embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 17c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 13 in Fig. 3. The connecting portion 17c is made of a material same as that of plate members 13a.

Referring to Figs. 8 and 9, an anastomosis member 18 according to an eighth embodiment of this invention comprises a pair of generally cylindrical bodies connected by a connecting portion 18c. Each of the generally cylindrical bodies is similar in structure to the generally cylindrical body of the anastomosis member 14 in Fig. 4. The connecting portion 18c is made of a material same

In the foregoing embodiments, the plate members 11a, 12a, 13a, and 14a are provided with the protrusions 11b, 12b, 13b, and 14b formed on both of the opposite surfaces thereof, respectively. Alternatively, the protrusions may be formed on only one of the opposite surfaces thereof. Each of the anastomosis members 11 through 18 is not restricted to the pattern described in each of the foregoing embodiments but may have any appropriate pattern as far as the diameter can flexibly be changed.

As a material of each of the plate members 11a, 12a, 13a, and 14a in the foregoing embodiments, use may be made of a stainless steel plate, a TiNi alloy and a TiNi-X alloy (X = Cr, V, Cu, Fe, Co, etc) having superelasticity at a living body temperature. Furthermore, use may also be made of a wide variety of shape memory alloys, such as a Cu-based alloy and a Fe-based alloy, as well as a beta Ti alloy. Taking the biocompatibility and the toxicity into consideration, the opposite surfaces of the plate members 11a, 12a, 13a, and 14a may be coated with titanium or the like.

Now, description will be made of several specific examples of the anastomosis of the first and the second blood vessels.

Referring to Fig. 10, a first example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of the anastomosis member 11 illustrated in Fig. 1. In the following description, the similar parts are designated by like reference numerals. It will be noted here that the size of the anastomosis member 11 in this example is slightly different from that mentioned in conjunction with Fig. 1.

As illustrated in Fig. 10, the anastomosis member 11 is arranged over a host blood vessel 33 as the first blood vessel and an artificial blood vessel 34 as the second blood vessel. An end portion of the artificial blood vessel 34 is

inserted into an end portion of the host blood vessel 33. The host and the artificial blood vessels 33 and 34 overlap each other to form an anastomosed site. The anastomosis member 11 is arranged in contact with intimae of the host and the artificial blood vessels 33 and 34.

Since the anastomosis member 11 comprises the plate members 11a connected in a zigzag pattern, the anastomosis member 11 can be brought into contact with the host and the artificial blood vessels 33 and 34 to expand the host and the artificial blood vessels 33 and 34 independently of each other. Because the protrusions 11b provide a large frictional force, the anastomosis member 11 can be securely engaged with the intimae of the host and the artificial blood vessels 33 and 34. Therefore, even under the beat of the artery, the dislocation of the host and the artificial blood vessels 33 and 34 with respect to each other can be avoided by the use of the anastomosis member 11.

By a hand of a surgeon, the anastomosis member 11 is inserted into lumens of the host and the artificial blood vessels 33 and 34. For example, if the artificial blood vessel 34 has a diameter of 6mm, the anastomosis member 11 is compressed to a reduced diameter of 6mm or less and then inserted into the lumen of the artificial blood vessel 34. Furthermore, the anastomosis member 11 is inserted also into the lumen of the host blood vessel 33. The host and the artificial blood vessels 33 and 34 are made to approach each other to form an overlapping portion. At this time, the anastomosis member 11 is self-expanded from a compressed state. Therefore, the anastomosis can be quickly and easily carried out.

From the foregoing description, it will readily be understood that the anastomosis members 12, 13, and 14 illustrated in Figs. 2 through 4 may also be used instead of the anastomosis member 11. In this case also, the end portions of the host and the artificial blood vessels 33 and 34 can be expanded independently of each other so that the anastomosis is reliably carried out.

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Referring to Fig. 11, a second example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of the anastomosis member 15 illustrated in Fig. 5. In the following description, similar parts are designated by like reference numerals. It will be noted here that the size of the anastomosis member 15 in this example is slightly different from that mentioned in conjunction with Fig. 5.

As illustrated in Fig. 11, the anastomosis member 15 is attached to the host blood vessel 33 and the artificial blood vessel 34. The anastomosis member 15 is arranged over the lumens of the host and the artificial blood vessels 33 and 34 to be anastomosed. The end portion of the artificial blood vessel 34 is inserted into the end portion of the host blood vessel 33.

When the anastomosis member 15 is arranged in the host and the artificial blood vessels 33 and 34, the anastomosis member 15 can expand the end portions of the host and the artificial blood vessels 33 and 34 independently of each other. Thus, the anastomosis is reliably carried out.

From the foregoing description, it will readily be understood that the anastomosis members 16, 17, and 18 illustrated in Figs. 6 through 8 may also be used instead of the anastomosis member 15. In this case also, the end portions of the host and the artificial blood vessels 33 and 34 can be engaged by the anastomosis member 15 to be expandable independently of each other. Thus, the anastomosis is reliably carried out.

Referring to Fig. 12, a third example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of a two-piece anastomosis device comprising a combination of the anastomosis member 11 in Fig. 1 and a woven tubular stent 36. In the following description, similar parts are designated by like reference numerals. It will be noted here that the size of the anastomosis member 11 in this example is slightly different from that mentioned in conjunction with Fig. 1.

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The stainless steel plate of the anastomosis member 11 is not restricted to SUS316 but may be any other appropriate product having a low rigidity and a flexibility. The material and the shape of the stent 36 are not restricted to those given in this embodiment but may be appropriately selected taking into account

Referring to Fig. 13, a fourth example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of a three-piece anastomosis device comprising a combination of the anastomosis member 11 in Fig. 1, a woven tubular stent 46, and an additional blood vessel 55. In this example also, the anastomosis member 11 serves as a securing member for securing the two blood vessels in the anastomosed state. In the following description, similar parts are designated by like reference numerals. It will be noted here that the size of the anastomosis member 11 in this example is slightly different from that mentioned in conjunction with Fig. 1.

Furthermore, the additional blood vessel 55 is arranged around the host and the artificial blood vessels 33 and 34 to cover the anastomosis member 11. The anastomosis member 11 and the additional blood vessel 55 are engaged with each other by the protrusions 11b. The opposite ends of the additional blood vessel 55 are fastened to the host and the artificial blood vessels 33 and 34 by a filament 57 or a strap as a fastening member. The protrusions 11b may be formed only on one surface of the anastomosis member 11 to be engaged with the host and the artificial blood vessels 33 and 34.

More specifically, the anastomosis member 11 comprises a strip-like plate member 11a made of a stainless steel plate (SUS316) subjected to

annealing and having a low rigidity. The plate member 11a has a thickness of 0.25mm. Each protrusion 11b has a height between 65 and 75 μ m and a diameter of 30 μ m. The protrusions 11b are formed at a pitch of 0.2mm.

In this example of the anastomosis, the anastomosis member 11 has an inner diameter of 8mm, an axial length of 10mm, and a width of 0.4mm. The anastomosis member 11 is flexibly variable in shape and in cylindrical diameter.

The stent 46 is made of a material similar to that of the stent 36 illustrated in Fig. 12 and has a lattice pattern. For example, the stent 46 is designed to have a cylindrical shape with a final expanding diameter of 7mm and an axial length of 20mm.

In the anastomosis, one axial half of the stent 46 is inserted into the lumen of the artificial blood vessel 34, for example, having an outer diameter of 8mm and an inner diameter of 6mm. Then, the host and the artificial blood vessels 33 and 34 are abutted to each other. Simultaneously, the other axial half of the stent 46 is inserted into the lumen of the host blood vessel 33. The anastomosis member 11 preliminarily arranged on the outside of the artificial blood vessel 34 is positioned to extend over the outer surfaces of both of the host and the artificial blood vessels 33 and 34. Likewise, the additional blood vessel 55 arranged on the outside of the artificial blood vessel 34 is positioned around the anastomosis member 11. The additional blood vessel 55 has an inner diameter of 8.1mm.

The opposite ends of the additional blood vessel 55 are fastened by the filament 57 as the fastening member to the outer surfaces of the host and the artificial blood vessels 33 and 34. The host and the artificial blood vessels 33 and 34 and the anastomosis member 11 are press-fitted by an internal pressure applied by the stent 46 and an external pressure applied by the additional blood vessel 55 fastened by the filament 57. At this time, the protrusions 11b are engaged with the host and the artificial blood vessels 33 and 34. Thus, the host

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and the artificial blood vessels 33 and 34 are prevented by the anastomosis member 11 from being dislocated with respect to each other even under the beat of the artery. Therefore, the anastomosis is reliably carried out. Since the additional blood vessel 55 and the filament 57 are fastened to each other, blood leakage from the anastomosed site to the outside is prevented.

The anastomosis in the above-mentioned example can be manually and quickly carried out by a surgeon so that the time of interrupting the blood flow can be shortened.

In this example of the anastomosis, the engaging force of the protrusions 11b acts only on the adventitia of each blood vessel which is relatively strong as compared with the intima. Thus, the load upon the host and the artificial blood vessels 33 and 34 is small as compared with the case where the inner surfaces are used in engagement. Furthermore, the host and the artificial blood vessels 33 and 34 need not overlap each other so that the anastomosis is possible even if the host and the artificial blood vessels 33 and 34 are substantially equal in diameter to each other. The anastomosis member 11 can relatively flexibly cope with the difference in size between the host and the artificial blood vessels 33 and 34.

The anastomosis member 11 is not restricted to the pattern described above but may have any pattern as far as the cylindrical diameter is flexibly variable. The material of the anastomosis member 11 is not restricted to the stainless steel plate but may be any appropriate material having a low rigidity and a flexibility.

The stent 46 is not restricted to the shape described above but may have any shape as far as an appropriate expanding force is provided so as to engage the host and the artificial blood vessels 33 and 34 and the anastomosis member 11 with one another. For example, use may be made of various kinds of stents typically used for expanding constricted portions of blood vessels.

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Referring to Figs. 15 and 16, a fifth example of the anastomosis will be described. Herein, the anastomosis is carried out by the use of a composite anastomosis device comprising a combination of the anastomosis member 111 in Fig. 14 and a woven tubular stent 136. The stent 136 is substantially similar to the stent 36 illustrated in Fig. 12.

The plate members 111a are sutured to the artificial blood vessel 34 with their surfaces having the protrusions 111b faced outward. In the example being illustrated in Fig. 16, eight plate members 111a are arranged on the outer surface of the artificial blood vessel 34 to form an octagonal shape around the center axis of the artificial blood vessel 34.

As illustrated in Fig. 15, the stent 136 is inserted into the lumen of the artificial blood vessel 34. The end portion of the artificial blood vessel 34 is inserted into the end portion of the host blood vessel 33. At this time, the plate members 111a are arranged between the blood vessels 33 and 34 overlapping each other. The protrusions 111b formed on the one surface of the plate members 111a sutured to the artificial blood vessel 34 are faced to the inner surface of the host blood vessel 33. The host blood vessel 33 and the plate members 111a are press-fitted by a pressing force of the stent 136 and the host

The shape and the number of the plate members 111a are not restricted to those given in this embodiment but may be appropriately selected so that the host and the artificial blood vessels 33 and 34 are reliably engaged by the protrusions 111b.

As described above, according to this invention, the anastomosis member having protrusions are arranged at the anastomosed site of the first and the second blood vessels so that the engaging force for engaging the first and the second blood vessels can be increased. The anastomosis member can achieve the safe anastomosis not only in a normal blood vessel but also in a diseased blood vessel. Furthermore, the anastomosis of the first and the second blood vessels can be quickly carried out.

The anastomosis member can be attached to the first and the second blood vessels which are abutted at their end faces to each other with the stent inserted into the lumens of the first and the second blood vessels. Therefore, it is possible to carry out the anastomosis for the first and the second blood

The anastomosis member can be arranged on the outside of the first and the second blood vessels. Furthermore, the additional blood vessel can be arranged on the outside of the anastomosis member and fastened by a filament or a strap in at least one position. With this structure, it is possible to exert a greater engaging force and to assure a sufficient fixing force. By the use of the additional blood vessel, it is possible to effectively prevent the blood leakage out of the anastomosed site.

The anastomosis member can be compressed and expanded by changing the angles of the angled portions of the connecting members. The plate member has a stress-strain characteristic different from that of the connecting member and is flexible and low in rigidity.

Finally, the anastomosis member is readily deformable in correspondence to the curvatures of the first and the second blood vessels. Therefore, it is possible to uniformly apply the pressure to the first and the second blood vessels without causing local concentration of the pressure.